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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,566	07/28/2000	Jonathan L. Goodwin	ATA-286	2331

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BOSTON, MA 02109

EXAMINER

BUI, VY Q

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/627,566

Applicant(s)

GOODWIN ET AL.

Examiner

Vy Q. Bui

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over BANAS et al (6,124,523) in view of DAVILA et al (6,296,661) .

As to claims 1 and 4, BANAS (Fig. 1, 1A, 2; column 1, lines 4-15; column 7, lines 12-17; claim 7) discloses a stent-graft implant comprising stent 22 sandwiched between inner cover 24 and outer cover 26 of expanded PTFE, inner cover 24 and outer cover 26 (each of a predetermined thickness) extend substantially along the entire length of the stent 22. BANAS does not disclose the expanded PTFE having IND of more than 100 microns. However, DAVILA (Figs. 6-7; claim 6) discloses a stent-graft implant comprising stent 60 sandwiched in graft material 70 of IND greater than 100 microns to allow a migration of cells to facilitate a more stable neointima on the surface of the stent-graft implant. In view of DAVILA's teaching, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to provide ePTFE of IND greater than 100 microns for the BANAS's inner cover 24 and outer cover 26 as this configuration of the inner and outer covers would facilitate forming of a more stable neointima on the surface of the BANAS's stent-graft implant.

As to claim 2, DAVILA (Fig. 6; column 5, lines 3-10) discloses inner cover 70 being folded at two ends of stent 60 over the outer surface of stent 60 to form outer cover.

As to claim 3, DAVILA (Fig. 6; column 5, lines 3-10) shows a first portion of the inner cover 70 folded over the outer surface of the stent 60 and a second portion of the inner cover 70 folded over the outer surface of the stent 60. DAVILA does not show the second portion of the inner cover 70 folded over the first portion of the inner cover 70. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to fold the second portion of

the inner cover 70 over the first portion of the inner cover 70 as this would provide more cover for the outer surface of the DAVILA's stent 60.

2. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over BANAS et al(6,124,523) in view of DAVILA et al (6,296,661) and further in view of EDWIN et al (6,039,755).

As to claim 5, BANAS and DAVILA disclose substantially all limitations as recited in the claims except for an average deployment pressure is less than 10 atm. However, EDWIN (column 3, lines 27-32; column 3, lines 61-63) discloses an ePTFE graft material suitable for use as a cover or liner for a stent-graft implant, which ePTFE is expanded under a pressure of less than 6 atm and most preferably between 2-3atm. In view of EDWIN 's teaching, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to construct BANAS's ePTFE covers to have the deployment pressure under 10 atm.

3. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over BANAS et al(6,124,523) in view of DAVILA et al (6,296,661) and further in view of LEWIS et (5,993,489).

In regard to claims 6 and 9, BANAS and DAVILA disclose substantially all limitations as recited in the claims except for the thickness of the cover is at least about .008 inch (or 0.2032 mm). LEWIS (abstract, lines 1-7; column 2, line 9-31) discloses an ePTFE vascular graft having radial thickness of about 0.25 mm or 0.010" and a GORE-TEX vascular graft material of radial thickness about 0.4 mm or 0.016". It would have been obvious one of ordinary skill in the art at the time of the invention was made to make BANAS's cover of radial thickness at least 0.008" (or 0.20 mm) as the process to make ePTFE of radial thickness at least 0.008" (0.20 mm) is well-known.

As to claim 7, DAVILA (Fig. 6; column 5, lines 3-10) discloses inner cover 70 being folded at two ends of stent 60 over the outer surface of stent 60 to form outer cover.

As to claim 8, DAVILA (Fig. 6; column 5, lines 3-10) shows a first portion of the inner cover 70 folded over the outer surface of the stent 60 and a second portion of the inner cover 70 folded over the outer surface of the stent 60. DAVILA does not show the second portion of the inner cover 70 folded over the first portion of the inner cover 70. It would have been obvious to one of ordinary

skill in the art at the time of the invention was made to fold the second portion of the inner cover 70 over the first portion of the inner cover 70 as this would provide more cover for the outer surface of the DAVILA's stent 60.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over BANAS et al(6,124,523) in view of DAVILA et al (6,296,661) and in view of LEWIS et al (5,993,489) as mentioned above and further in view of EDWIN et al (6,039,755).

As to claim 10, BANAS and DAVILA and LEWIS disclose substantially all limitations as recited in the claims except for an average deployment pressure is less than 10 atm. However, EDWIN (column 3, lines 27-32; column 3, lines 61-63) discloses an ePTFE graft material suitable for use as a cover or liner for a stent-graft implant, which ePTFE is expanded under a pressure of less than 6 atm and most preferably between 2-3 atm. In view of EDWIN 's teaching, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to construct BANAS's ePTFE covers to have the deployment pressure under 10 atm.

Response to Amendment

The amendment filed on 3/6/2002 under 37 CFR 1.131 has been carefully considered but is ineffective to overcome the rejections in previous "Office Action" (paper 5). The rejections in previous "Office Action" therefore remain effective.

As to claims 1 and 6, basically, the Applicants contend that the stent-graft device in the present invention comprises a stent and at least a cover (or graft) of "a predetermined thickness" or "a thickness of at least 0.008" and "an average IND of greater 100 microns" is novel over the prior art of reference because the stent-graft device as claimed is so constructed to reduce a deployment pressure necessary to expand the stent, and DAVILA's cover/graft having IND of greater 100 microns for a different reason: to allow for the migration of cells to facilitate a more stable neointima on the surface of the stent-graft device.

The fact that the Applicants use the cover/graft in the present stent-graft device as claimed for a different purpose (to reduce a deployment pressure necessary to expand the stent) from DAVILA (to allow for the migration of cells to facilitate a more stable neointima on the surface of the stent-graft device) does not alter the conclusion that the cover/graft as claimed would be prima facie obvious from the cover/graft disclosed in the DAVILA reference." In re Lintner, 173 USPQ 560.

Moreover, the combination of BANAS and DAVILA produces a device including every structural limitation as recited in the claims and therefore there is no structural difference between the device combined of BANAS and DAVILA and the device as claimed. It has been held that a recitation with respect to the purpose in which a claimed device is intended to be employed does not differentiate the claimed apparatus from a prior art device satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Similar reasoning is applicable for other rejections presented above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is (703) 306-1382.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano, can be reached at (703) 308-2496. The fax number for this Unit is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at (703) 308-0858

VQB

June 2, 2002.


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
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